

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

June 27, 2013

EPA Reg#: 1677-EUN		DP Barcode: 409191	
		Submission #: 930239	
Product name: Hydris Mineral Activator Tablet		Registrant: Ecolab, Inc.	
Reviewer's name: Juan F. Negrón		AD/PSB/CTT- Product Chemistry Review	
Agency due date: 07/22/13		PSB received date: 02/14/13	
CTT received date: 02/14/13		Science due date: 05/28/13	
Formulation type: MUP		Sub data package due date: 06/07/13	
Integrated system: <input checked="" type="checkbox"/>		Non integrated system: <input type="checkbox"/>	Food use: <input type="checkbox"/> Non food use: <input checked="" type="checkbox"/>
Action Code: A532		Date Completed: 06/27/13	
PC Code(s)	CAS #(s)	Active Ingredient Names	% wt (label)
013905	7647-14-5	Sodium chloride	99.97
Molecule structure (optional):		Na ⁺ Cl ⁻	
MRIDs: 49049500, & 49049501			
Approver: Karen P. Hicks		Approved date: 07/01/13	

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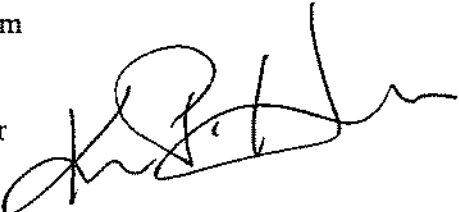
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MORANDUM

Subject: Product Chemistry Review for EPA Reg # 1677-EUN.
Product Name: Hydrys Mineral Activator Tablet
DP Barcode: 409191

From: Juan F. Negrón, Chemist 
Product Science Branch, CT Team
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader 
Product Science Branch
Antimicrobials Division (7510P)

To: Demson Fuller / Killian Swift
PM Team 32

APPLICANT: Ecolab, Inc.
Action code: A532
Due date: 07/22/13

**Product Formulation
Active Ingredient**

	% by wt.
Sodium chloride	99.97

BACKGROUND:

The registrant, Ecolab, Inc., is requesting a new registration. The product will be used with a pesticide device that has a three chamber electrolytic cell to generate a sodium hypochlorite solution to be used onsite with no sale or distribution. The Product Chemistry Reviewer has reviewed the following documents:

- A letter, dated 01/30/13 MRID # 49049500.
- Transmittal document, dated 01/30/13.
- Application for pesticide registration dated 01/30/13.
- Certification with respect to citation of data, dated 01/30/13.
- A draft label, pin punched on 02/01/13.
- Confidential Statements of Formula (CSFs), dated 11/30/13, for the basic and alternate formulations.
- Data matrix, dated 01/30/13.
- Certification with respect to label integrity, dated 01/28/13.
- A study titled "ECOLAB SALT Chemical Characterization" MRID # 49049501.

FINDINGS:

1. The CSFs, dated 01/30/13, for the basic and alternate formulations are obsolete.
2. The CSF, dated 06/23/13, for the basic formulation is revised. The registrant decided not to submit an alternate formulation at the present time.
3. The CSF and the label have the same nominal concentration for the active ingredient (AI).
4. The component meets the EPA Standard Certified Limits.
5. The registrant conducted a five batch of analysis to meet the "OPPTS 830.1700 Preliminary Analysis" and the results are as follow:

Summary of active ingredient (AI) content:					
Batch #	8/16/10	12/20/11	5/1/12	13515-7a	13515-7b
Average % Cl ⁻ as NaCl	99.02	98.97	98.97	98.90	99.04
Total Average % NaCl 98.98					
Comment: All assays meet the EPA Standard Certified Limits.					

6. The title of the study MRID # 49049501 suggested a chemical characterization for the product. However, there were no indications that the chemical characterization of the product was conducted for a specific purpose such as to satisfy the efficacy study. The study contains the 830 Groups (A & B) guidelines.

7. The 830.1900 Submittal of samples guideline indicated that a sample is not required because the Agency did not requested such.
8. The registrant has indicated that the 830.6317 Storage Stability and 830.6320 Corrosion Characteristic guidelines are not required because the product is a TGAI.

CONCLUSION:

The CSF, dated 06/23/13, for the basic formulation is acceptable. The OPPTS 830 Groups "A & B" have been met with the exception of the one-year storage stability and corrosion characteristic guidelines. The product chemistry package is acceptable. See table below.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system ☐
- Are all TGAs used registered? Yes ☒ No ☐
- Integrated formulation system ☒
- If "ME-TOO," specify EPA Reg. No. of existing product:

b. Clearance of inerts for non-food:

Yes ☒ No ☐

c. Physical state of product:

Solid

d. The chemical IDs and analytical information (including that for the TGAs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes ☒ No ☐

e. The NCs and CLs are acceptable.

Yes ☒ No ☐

f. Active ingredients

	<u>NC</u> (%)	<u>LCL</u> (%)	<u>UCL</u> (%)
Sodium chloride	99.97	96.97	103

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes ☐ No ☐ Not applicable ☒
- Have all impurities of $\geq 0.1\%$ in the product been identified?
Yes ☐ No ☐ Not applicable ☒

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes ☒ No ☐

b. The formula contains one of the following:

- | | | |
|--|------------------------------|--|
| • 10% or more of a petroleum distillate: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • 1.0% or more of methyl alcohol: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • sodium nitrite at any level: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • a toxic List 1 inert at any level: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • arsenic in any form: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes ☐ No ☐ Not applicable ☒

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes ☐ No ☐ Not applicable ☒

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes ☐ No ☐

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes ☐ No ☒

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity ¹	A	49049501
830.1600 Description of Materials	A	49049501
830.1620 Production Process ²	A	49049501
830.1650 Formulation Process ³	N The registrant indicated that it is not applicable because the product is an integrated system.	49049501
	A See page 36 of 42 from the new proposed study.	
830.1670 Formation of Impurities ⁴	N The registrant indicated that the impurities are < 0.1% by weight @ end-use product.	49049501
	A For MUP the impurities are less than 0.1%; [REDACTED] is the major impurity with traces of [REDACTED] This is a food grade salt product.	
830.1700 Preliminary Analysis ⁵	A (see findings for more information)	49049501
830.1750 Certified Limits ⁶	A See CSF.	49049501
830.1800 Enforcement Analytical Method ⁷	A	
830.1900 Submittal of Samples	N Registrant has indicated that is not required because the Agency did not request the submittal of samples.	49049501
	A Available upon request. Registrant updated the information.	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable; NR= not required; G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

¹See Confidential Appendix A for additional information.

²For MP/EP products produced by an integrated formulation system.

³For products from a TGAI or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	White	49049501
830.6303 Physical State	A	Opaque solid	49049501
830.6304 Odor	A	None	49049501
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NR	<i>[Not required for manufacturing-use products.]</i>	49049501
830.6314 Oxidation/Reduction; Chemical Incompatibility	A	Slightly reactive or incompatible with metals and acids.	49049501
830.6315 Flammability/Flame Extension	NA	The product does not contain any flammable ingredients.	49049501
830.6316 Explodability	NA	Not applicable since the product does not contain any explosive ingredients.	49049501
830.6317 Storage Stability	N	Registrant suggested that the product is a TGAI.	49049501
	A	In progress.	
830.6319 Miscibility	A	Not applicable since the product is not intended for use with oil or a non-polar solvent.	49049501
830.6320 Corrosion Characteristics	N	Registrant suggested that the product is a TGAI.	49049501
	A	In progress.	
830.6321 Dielectric Breakdown Voltage	NR	<i>[Not required for manufacturing-use products.]</i>	49049501
830.7000 pH	A	The pH of an aqueous solution of sodium chloride is neutral (7). The pH of a saturated sodium chloride solution is 6.7 – 7.3	49049501
830.7050 UV/Visible Absorption	NR	<i>[Not required for manufacturing -use products.]</i>	49049501
830.7100 Viscosity	A	Product is not a liquid.	49049501
830.7200 Melting Point/Melting Range	NR	<i>[Not required for manufacturing -use products.]</i> However, the registrant indicated 804 °C.	49049501
830.7220 Boiling Point/Boiling Range	NR	<i>[Not required for manufacturing -use products.]</i> However, the registrant indicated 1413 °C.	49049501
830.7300 Density/Relative Density/Bulk Density	A	2.17 g/mL from MSDS information. The MSDS indicated that the product is a tablet with an AI concentration > 50%.	49049501

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7370 Dissociation Constants in Water	NR	<i>[Not required for manufacturing -use products.]</i>	49049501
830.7520 Particle Size, Fiber Length, and Diameter Distribution	NR	<i>[Not required for manufacturing -use products.]</i> The product is neither a powdered-type nor a fibrous product.	49049501
830.7550/830.7560/830.7570 Partition Coefficient	NR	<i>[Not required for manufacturing -use products.]</i>	49049501
830.7560 Partition Coefficient (n-Octanol/Water), Generator Column Method	NR	<i>[Not required for manufacturing -use products.]</i>	49049501
830.7570 Partition Coefficient (n-Octanol/Water), Estimation by Liquid Chromatography	NR	<i>[Not required for manufacturing -use products.]</i>	49049501
830.7840/830.7860 Water Solubility	NR	<i>[Not required for manufacturing -use products.]</i>	49049501
830.7860 Water Solubility (Generator Column Method)	NR	<i>[Not required for manufacturing -use products.]</i>	49049501
830.7950 Vapor Pressure	NR	<i>[Not required for manufacturing -use products.]</i>	49049501

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; NR= not required; G=data gap.